Sensory Evaluation of ISOMALT, MANNITOL and SUCROSE with Respect to the Manufacture of Organoleptically Attractive Dosage Forms

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INTRODUCTION

Patient friendly dosage forms are a prequisite for the effective treatment of diseases especially when therapy time is prolonged. If the taste attributes of the medicine play a determining role, pharmaceutical excipients like SUCROSE, MANNITOL and recently ISOMALT are often used taking into account their sensory attributes such as sweetness and texture.

In this respect SUCROSE is of significant importance, as it is an integral part of our food since primeval times and has become the epitome of the intimate taste impression for “sweet“. Therefore SUCROSE serves as the benchmark for all comparisons of sweetening power and the taste impression of sweeteners [1].

In the development course of pharmaceutical dosage forms, sugar alcohols have become the prefered choice over SUCROSE when properties like suitability for diabetics and tooth friendliness are in the foreground.

MANNITOL is used because of its low hygroscopicity and chemical inertness. Moreover it is applied to taste mask unpleasant sensorial properties of active pharmaceutical ingredients [2].

ISOMALT is a mixture of two disaccharide alcohols and is the only sugar alcohol that is derived from SUCROSE. It consists of the components: 6-O-α-D-glucopyranosyl-D-sorbitol (GPS) and 6-O-α-D-glucopyranosyl-D-mannitol dihydrate (GPM). Monographs of ISOMALT are described in current editions of the Ph.Eur. and USP/NF. Two different types of ISOMALT with good flow and compaction properties are marketed by BENEO-Palatinit, whereby galenIQ™ 720 exhibits a ratio of GPS:GPM 1:1 and galenIQ™ 721 exhibits a ratio of 3:1.

As the water solubility of GPS is higher compared to that of GPM the products differentiate themselves in their water solubility [3].

AIM

Sensory evaluation of excipients with respect to the following questions:

A. Which of the sugar substitutes sensory profile is the closest to sugar?
B. How does ISOMALT differ from MANNITOL?
C. Do sensory differences exist between both ISOMALT-grades?

MATERIALS

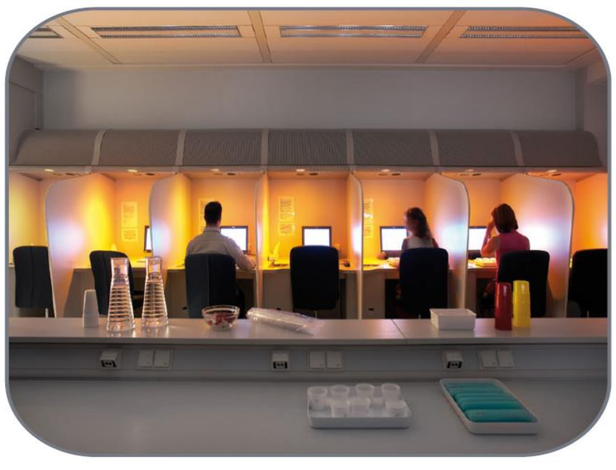
Table 1: Bulk characteristics of investigated products

	SUCROSE (agglomerated)	ISOMALT (1 GPS : 1 GPM) (agglomerated)	ISOMALT (3 GPS : 1 GPM) (agglomerated)	MANNITOL (agglomerated)
Brand name	Comprizucker O	galenIQ™720	galenIQ™721	Competitor
Manufacturer	(Südzucker AG)	(BENEO-Palatinit GmbH)	(BENEO-Palatinit GmbH)	(Competitor)
Batch Nr.	L117993900	IMUL929	OMUL848	M365819530
Bulk density [g/l]	600	410	405	510
Particle size distribution				
d_{10} [µm] d_{50} [µm] d_{90} [µm]	130 280 500	80 210 350	90 220 370	80 230 460

METHODS

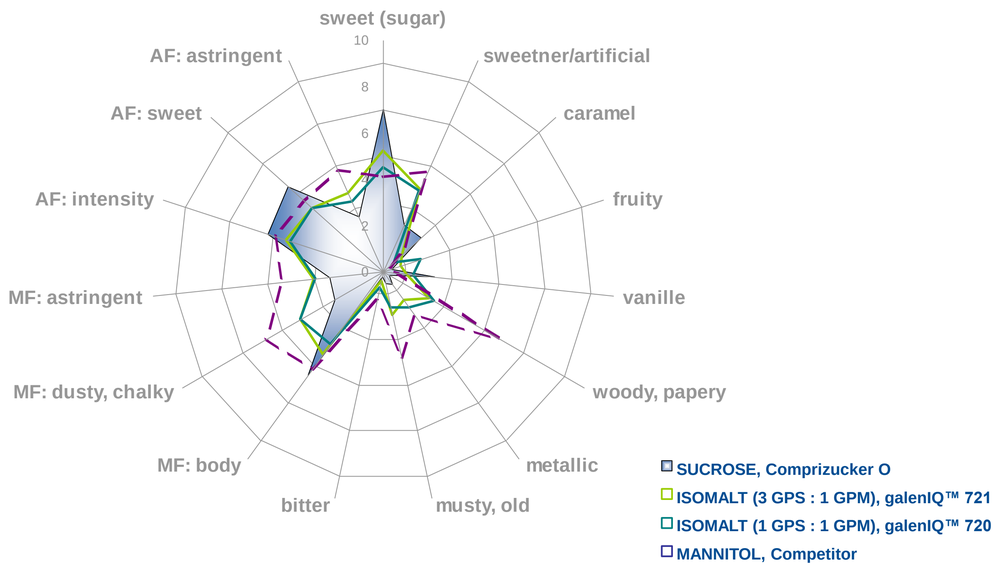
Descriptive attribute sensory evaluation

- 16 selected and trained panelists
- Evaluation of blind coded samples (1.6 g, dry) under standardized test conditions
- Generation of the list of descriptive attributes by the panel
- Assessment of the intensities of each descriptive attribute on a 10-point scale, where 0 corresponds to discernible and 10 corresponds to very discernible.
- In addition the sensation of the sweetness was evaluated qualitatively



RESULTS

Diagram 1: Comparison of SUCROSE, MANNITOL and ISOMALT; MF = Mouthfeel; AF = Aftertaste



COMPARISON ISOMALT vs. MANNITOL

Taste
MANNITOL is perceived as slightly more artificially sweet. Moreover it exhibits a significantly more woody/papery, musty/old and metallic taste. It is described qualitatively that the sweetness develops more slowly, which perhaps can be refered to by its slower dissolution in the mouth.

Mouthfeel (MF)
Main differences are the dustier, chalkier and more astringent mouthfeel of MANNITOL in comparison to ISOMALT.

Aftertaste (AF)
Concerning aftertaste MANNITOL and ISOMALT can be distinguished mainly in the more astringent mouthfeel of MANNITOL, not so much in the intensity of their sweetness.

COMPARISON OF ISOMALT-grades (galenIQ™720 vs. galenIQ™721)

Taste
Overall both ISOMALT-grades can be described as similar concerning their sensorial properties. galenIQ™721 is perceived as slightly more sweet, whereas galenIQ™ 720 is described qualitatively as offering the sweetness faster and as being slightly more fruity.

Mouthfeel (MF)
galenIQ™721 exhibits slightly more body compared to galenIQ™720.

Aftertaste (AF)
There are virtually no differences in aftertaste for both grades of ISOMALT.

QUALITATIVE DESCRIPTION OF THE SENSATION OF SWEETNESS

SUCROSE (Comprizucker O)
Almost immediate perception of the sweetness, that decreases only slowly and lasts long, even after swallowing.

ISOMALT GPS:GPM 3:1 (galenIQ™721)
The sweetness does not appear as fast as with SUCROSE and is also not as intensive. The intensity decreases faster and does not last as long.

ISOMALT GPS:GPM 1:1 (galenIQ™720)
The sweetness appears fast but is not as intensive and does not last as long compared to SUCROSE. A slightly fruity flavor develops.

MANNITOL (Competitor)
Due to the fact that the powder does not dissolve easily the sweetness develops more slowly. The sweetness is less intense compared to SUCROSE.
Many panelists describe the sweetness to be artificial.

CONCLUSION

- **Both ISOMALT-grades are significantly more sugar-like in comparison to MANNITOL**
- **MANNITOL exhibits stronger less-desirable tastes like woody, papery and metallic. Moreover it is significantly more dusty, chalky and astringent compared to SUCROSE and ISOMALT**
- **Overall both ISOMALT-grades have similar sensory profiles**

LITERATURE

[1] Jung, H.-W.; *Handbuch Süßungsmittel Eigenschaften und Anwendung*; ed. Rosenplenter, K.; Nöhle, U.; Behr´s Verlag 2007; Kapitel 3, Zucker, S. 75
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[3] Bolhuis, G.K.; Armstrong, N.A. ; *Excipients for direct compaction – an update;* Pharm. Dev. Technol. 2006, *11* (1), S. 111-124